

**NON-BLOOD
BIOLOGICAL PRODUCT DEVIATION CODES
FY03**

CBER enters the fourth level detail code (e.g., A, B, C) into the database as standardized remarks to further describe some of the codes, in particular miscellaneous codes. These codes are not included on the BPD report form.

IM--** INCOMING MATERIAL SPECIFICATIONS**

IM-10-**-** Miscellaneous

IM-10-01 Other

IM-12-**-** Container

IM-12-01 Specifications not met

IM-12-02 Defective

IM-13-**-** Closures

IM-13-01 Specifications not met

IM-13-02 Defective

IM-14-**-** Source or raw material does not meet specifications or otherwise found to be unsuitable

IM-14-01 Other

IM-14-02 Contains precipitate

IM-14-03 Contaminated with microorganism

IM-14-04 Contaminated with mold

IM-14-05 Impurities exceed specification

IM-14-06 Testing deviation

IM-14-07 Stored or shipped at incorrect temperature or lack of controlled temperature

PC--** PROCESS CONTROLS**

PC-20-**-** Miscellaneous

PC-20-01 Other

PC-21-**-** Manufacturing or processing performed using incorrect parameters

PC-21-01 Other

PC-21-02 Incorrect temperature

PC-21-03 Filling not performed according to specifications

PC-21-04 Aseptic processing procedures not performed according to specifications

PC-22-**-** Process/Procedure

PC-22-01 Other

PC-22-02 Interruption of process

PC-22-03 Environmental monitoring excursions

PC-22-04 Equipment not qualified

PC-22-05 Sanitization not performed or performed incorrectly

PC-22-06 Failed media fill

PC-23-**-** Process Water - specification not met

PC-23-01 Other

- PC-23-02 Water for injection
- PC-23-03 Purified water
- PC-24-** Bulk material does not meet specifications or otherwise found to be unsuitable
 - PC-24-01 Other
 - PC-24-02 Contains precipitate
 - PC-24-03 Contaminated with microorganism
 - PC-24-04 Contaminated with mold
 - PC-24-05 Impurities exceed specification
 - PC-24-06 Stored at incorrect temperature
 - PC-24-07 Stored for an excessive hold time
- TE-**-** TESTING
 - TE-30-** Miscellaneous
 - TE-30-01 Other
 - TE-31-** Safety
 - TE-31-01 Performed incorrectly
 - TE-31-02 Not performed or not documented
 - TE-32-** Purity
 - TE-32-01 Performed incorrectly
 - TE-32-02 Not performed or not documented
 - TE-33-** Potency
 - TE-33-01 Performed incorrectly
 - TE-33-02 Not performed or not documented
 - TE-34-** Sterility
 - TE-34-01 Performed incorrectly
 - TE-34-02 Not performed or not documented
 - TE-35-** Identity
 - TE-35-01 Performed incorrectly
 - TE-35-02 Not performed or not documented
 - TE-36-** Stability
 - TE-36-01 Performed incorrectly
 - TE-36-02 Not performed or not documented
- LA-**-** LABELING
 - LA-40-** Miscellaneous
 - LA-40-01 Other
 - LA-41-** Package insert
 - LA-41-01 Incorrect
 - LA-41-02 Missing
 - LA-41-03 Not current or approved
 - LA-42-** Product label
 - LA-42-01 Incorrect
 - LA-42-02 Missing
 - LA-43-** Carton label
 - LA-43-01 Incorrect

- LA-43-02 Missing
- LA-44-** Expiration date
 - LA-44-01 Extended
 - LA-44-02 Missing
- LA-45-** Lot number
 - LA-45-01 Incorrect
 - LA-45-02 Missing
- LA-46-** Storage temperature
 - LA-46-01 Incorrect
 - LA-46-02 Missing
- LA-47-** Administration route
 - LA-47-01 Incorrect
 - LA-47-02 Missing
- LA-48-** Concentration or volume
 - LA-48-01 Incorrect
 - LA-48-02 Missing

PS--** PRODUCT SPECIFICATIONS**

- PS-50-** Miscellaneous
 - PS-50-01 Other
- PS-51-** Product specification not met
 - PS-51-01 Other
 - PS-51-02 Contains precipitate
 - PS-51-03 Contaminated with microorganism
 - PS-51-04 Contaminated with mold
 - PS-51-05 Impurity levels
 - PS-51-06 Moisture
 - PS-51-07 Preservative content
 - PS-51-08 Potency
 - PS-51-09 Appearance
 - A – Cloudy
 - B - Hemolyzed
 - PS-51-10 Fill volume
- PS-52-**Component packaged with final product did not meet specifications
 - PS-52-01 Other
 - PS-52-02 Contains precipitate
 - PS-52-03 Contaminated with microorganism
 - PS-52-04 Contaminated with mold
 - PS-52-05 Fill volume
- PS-53-** Stability testing failed
 - PS-53-01 Other
 - PS-53-02 Potency
 - PS-53-03 Preservative
 - PS-53-04 Container closure integrity
 - PS-53-05 Chemical analysis/purity
- PS-54-** Administration set (packaged with product) incorrect or incomplete

- PS-54-01 Other
- PS-54-02 Incorrect or missing label
- PS-54-03 Defective
- PS-54-04 Expired

QC-**-** QUALITY CONTROL AND DISTRIBUTION

- QC-60-**-** Miscellaneous
 - QC-60-01 Other
- QC-61-**-** Product distributed inappropriately
 - QC-61-01 Other
 - QC-61-02 Product distributed prior to completion of required testing
 - QC-61-03 Product distributed prior to CBER approval of a PAS
 - QC-61-04 Product distributed less than 30 days after submission of CBE-30
 - QC-61-05 Product distributed prior to validation of process
 - QC-61-06 Outdated product distributed
- QC-62-**-** Shipping and storage
 - QC-62-01 Other
 - QC-62-02 Product shipped at incorrect temperature
 - QC-62-03 Product stored at incorrect temperature
- QC-63-**-** Product identified as unacceptable, and not quarantined
 - QC-63-01 Other

MI-**-** MISCELLANEOUS

- MI-70-**-** Miscellaneous
 - MI-70-01 Other